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From-LAHIVE & COCKFIELD, LLP

6177424214

T-574 P.08/16 F-056

Serial No.: 08/300510

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AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application.

1-133. (Cancelled)

- 134. (Currently amended) A method of treating allergy in humans comprising administering to a human at least one therapeutic composition in an amount sufficient to down regulate a protein allergen specific immune response in the human, wherein the therapeutic composition comprises at least one isolated pept de having a defined sequence of amino acid residues, said peptide comprising at least about 20% of the T cell epitopes of the protein allergen, said peptide being reproducible and not being conjugated to any other molecule, said peptide having a mean T cell stimulation index of at least about 3.5 determined in an in vitro T cell proliferation assay with T cells obtained from a population of humans sensitive in said allergen, and said peptide having a positivity index of at least 150 as determined in an in vitro T cell proliferation assay with T cells obtained from a population of humans sensitive to said allergen, wherein the method as in any one of claims 10:-109 comprising administering the composition is first administered at an initial treatment of three to six dosages of said composition once a week for 3-6 three to six weeks.
- 135. (Currently amended) The method of claim 134 further comprising administration an additional a second administration of said composition at intervals of between about three months and one year after said initial first administration treatment.
- 136. (Currently amended) The method as in any one of claims 134 or 145 108-109, further comprising the step of increasing the dosage with each subsequent additional dosage of said composition.
- 137. (Currently amended) A method of treating allergy in humans comprising administering to a human at least one therapeutic composition in an amount sufficient to down regulate a protein allergen specific immune response in the

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human, wherein the therapeutic composition comprises at least one isolated peptide having a defined sequence of amino acid residues, said peptide comprising at least about 20% of the T cell epitopes of the protein allergen, said peptide being reproducible and not being conjugated to any other molecule, said peptide having a mean T cell stimulation index of at least about 3.5 determined in an in vitro T cell proliferation assay with T cells obtained from a population of humans sensitive to said allergen, and said peptide having a positivity index of at least 150 as determined in an in vitro T cell proliferation assay with T cells obtained from a population of humans sensitive to said allergen, method as in any one of claims 108-109, comprising the step of decreasing the dosage with each subsequent additional desage of said composition.

138. (Currently amended) The method as in any one of claims 108-109 134 or 145, wherein treatment results in a statistically significant improvement in symptoms caused by the human's immune response to the protein allergen.

139-144. (Cancelled)

- 145. (New) The method of claim 134, wherein the peptide comprises 50 amino acid residues or less.
- 146. (New) The method as in any one of claims 134 or 145, wherein the peptide is modified by at least one amino acid substitution, addition or deletion, said peptide comprising a T cell epitope recognized by a T cell receptor specific for the protein allergen.
- 147. (New) The method as in any one of claims 134 or 145, wherein the peptide is purified to at least 90% purity.
- 148. (New) The method of claim 147, wherein the peptide is purified to at least 95% purity.
- 149. (New) The method of claim 148, wherein the peptide is purified to at least 97%

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purity.

- 150. (New) The method as in any one of claims 134 or 145, wherein the peptide is at least about 12 amino acid residues in length,
- 151. (New) The method as in any one of claims 134 or 145, wherein the at least one peptide comprises at least two peptides.
- (New) The method as in any one of claims 134 or 145, wherein the protein allergen 152. is selected from the group consisting of: a protein allergen of the genus Dermatophagoides; a protein allergen of the genus Felix; a protein allergen of the genus Ambrosia; a protein allergen of the genus Lolium; a protein allergen of the genus Cryptomeria; a protein allergen of the genus Alternaria; a protein allergen of the genus Alder; a protein allergen of the genus Betula; a protein allergen of the genus Quercus; a protein allergen of the genus Olea; a protein allergen of the genus Artemisia; a protein allergen of the genus Plantago; a protein allergen of the genus Parietaria; a protein allergen of the genus Canine; a protein allergen of the genus Blattella; a protein allergen of the genus Apis; a protein allergen of the genus Cupressus; a protein allergen of the genus Juniperus; a protein allergen of the genus Thuya; a protein allergen of the genus Chamaecyparis; a protein allergen of the genus Periplaneta; a protein allergen of the genus Agropyron; a protein allergen of the genus Secale; a protein allergen of the genus Triticum; a protein allergen of the genus Dactylis; a protein allergen of the genus Festuca; a protein allergen of the genus Poa; a protein allergen of the genus Avena; a protein allergen of the genus Holcus; a protein allergen of the genus Anthoxanthum; a protein allergen of the genus Arrhenatherum; a protein allergen of the genus Agrostis; a protein allergen of the genus Phleum; a protein allergen of the genus Phalaris; a protein allergen of the genus Paspalum; and a protein allergen of the genus Sorghum.
- 153. (New) The method of claim 152, wherein the protein allergen is selected from the group consisting of: Derp I; Derp II; Derp III; Derp VII; Derf II; Derf III; Derf VIII; Fel d I; Amb a I.1; Amb a I.2; Amb a I.3; Amb a I.4; Amb a II; Lol p I.

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Lot $p ext{ II}$; Lot $p ext{ IV}$; Lot $p ext{ IV}$; Lot $p ext{ IV}$ (Lot $p ext{ V or Lot } p ext{ Ib}$); Cry $j ext{ II}$; Can $f ext{ II}$; Can $f ext{ II}$; Jun $s ext{ I}$; Jun $s ext{ I}$; Jun $s ext{ I}$; Dac $g ext{ I}$; Poa $p ext{ I}$; Phl $p ext{ I}$; and Sor $h ext{ I}$.

- 154. (New) The method as in any one of claims 134 or 145, wherein the composition further comprises a pharmaceutically acceptable carrier.
- 155. (New) The method of claim 154, wherein the pharmaceutically acceptable carrier comprises at least one excipient selected from the group consisting of sterile water, sodium phosphate, mannitol, sorbitol, sodium chloride, and any combination thereof.
- 156. (New) The method as in any one of claims 134 or 145, wherein the composition ... soluble in an aqueous solution at a physiologically acceptable pH.
- 157. (New) The method as in any one of claims 134 or 145, wherein said administering comprises a route of administration selected from the group consisting of oral, intravenous, sublingual, transdermal, inhalation, subcutaneous and rectal.
- 158. (New) The method of claim 157, wherein said administering comprises subcutaneous administration of said composition.
- 159. (New) The method as in any one of claims 134 or 145, wherein said composition is administered without adjuvant.